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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,573	11/21/2003	Jen-Leih Wu	33151-188802	3665
23639 7590 01/29/2007 BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO CENTER 18 FLOOR SAN FRANCISCO, CA 94111-4067			EXAMINER MCGILLEM, LAURA L	
			ART UNIT	PAPER NUMBER
			1636	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/29/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/717,573	Applicant(s) WU ET AL.	
	Examiner Laura McGillem	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 3-14 are under examination.

Drawings

It is noted that new drawing for Figure 11 has been submitted on 8/15/2006, and the objection to the drawing is now withdrawn.

Specification

It is noted that the specification has been amended regarding use of Trademarks on page 15, and the objection to the specification is now withdrawn.

Claim Objections

Claim 1 is objected to because of the following informalities: claim 1 has been previously amended to include the phrase "from a fish" indicated by underlining. In the present claim set, the phrase "from a fish" is still underlined. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Applicants have amended claims 12 and 14 to replace the phrase "basal promoter" with the phrase "core promoter." Applicant's arguments see Remarks/Arguments (page 12), filed 8/15/2006, with respect to claims 12-14 have been

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fully considered and are persuasive. The rejection of claims 12-14 under the second paragraph of 35 U.S.C. § 112 has been withdrawn.

The rejections of claims 7-9 and 10-11 under 35 U.S.C. 112, second paragraph have been withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is being maintained for reasons of record in the previous Office Action mailed 5/16/2006 and for reasons outlined below.

Applicants have amended claim 1 to recite "an isolated polynucleotide comprising a liver-specific expression control sequence from a fish that modulates expression of a vertebrate liver fatty acid binding protein (L-FABP)." Applicants submit that the amended phrase is fully supported in the specification by SEQ ID NOS: 1-3. Applicants have also amended claims 6, 8, 10 and 11 to recite "a functional variant." Applicants submit that the specification has provided detailed descriptions for "functional variants" on page 10, lines 14-17 and on page 12, lines 4-14.

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Applicant's arguments filed 8/15/2006 have been fully considered but they are not persuasive.

The addition of the phrase "from a fish" limits the polynucleotide sequence comprising the liver specific expression control sequence from a fish, however the genus of fish liver specific expression control sequence is still a very large genus, since fish species number in the tens of thousands and include both known and unknown species of fish. The addition of the phrase "a functional variant" as defined in the disclosure does not provide a sufficiently limited definition of the claimed polynucleotide because the specification teaches that functional variants are sequences that are at least about 70%, 80%, 90%, 95% or 98% identical to identified sequences (see paragraph 0038 of the published application). Further, functional variants can include polymorphisms, SNPs, allelic variants and mutants, and can comprise one or more additions, insertions, deletion, substitutions, transitions, transversions, inversions, chromosomal translocations and alternative splicing variants and any combinations thereof. Therefore, functional variants having at least 80% identity to SEQ ID NO:1-3 encompass a very large genus of polynucleotides. The sequences of liver specific expression control sequence are fully described for only a few species, including fish, rats and mice. The specification does not describe how the disclosed structures of the liver specific expression control sequence relates to the structure of liver-specific expression control sequences that are at least about 70%, 80%, 90%, 95% or 98% identical to identified sequences. The specification does not establish a relationship between the structures of functional variants of a liver-specific expression control

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sequence and the claimed function of modulation of L-FABP expression. Therefore, the rejection of claims 1 and 3-14 under 35 U.S.C. 112, first paragraph is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhong et al (Genomics, 1998, Feb 15;48(1):136-8).

This rejection is being maintained for reasons of record in the previous Office Action mailed 5/16/2006 and for reasons outlined below.

Applicants submit that for anticipation under 35 U.S.C. § 102, the reference "must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present." (MPEP §706.02, IV. Distinction between 35 U.S.C. 102 and 103, page 700-21). The Federal Circuit has held that prior art is anticipatory only if every element of the claimed invention is disclosed in a single item of prior art in the form literally defined in the claim. See e.g., *Jamesbury Corp. v. Litton Indus. Products*, 756 F.2d 1556, (Fed. Cir. 1985); See also *Atlas Powder Co. v. DuPont*, 750 F.2d 1569, (Fed. Cir. 1984); *American Hospital Supply. Travenol Labs*, 745 F.2d 1 (Fed. Cir. 1984).

Applicants submit that Zhong describes the construction of a zebrafish genomic library from zebrafish embryos in yeast artificial chromosomes but that Zhong does not disclose "an isolated polynucleotide comprising a liver-specific expression control sequence from a fish that modulates expression of a vertebrate liver fatty acid binding protein (L-FABP)," as recited in claim 1. Applicants respectfully disagree that Zhong would inherently contain "a basal promoter of a zebrafish isolated polynucleotide comprising a liver-specific expression control sequence from upstream of a gene for L-FABP". Applicants submit that although Zhong's library provides coverage of the zebrafish genome in about 17,000 clones with an average insert size of 470 kb, there is no guarantee that among these clones, "the liver-specific expression control sequence from a fish that modulates expression of a vertebrate liver fatty acid binding protein (L-FABP)" are included. Applicants submit that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of the result or characteristic. *In re Rijckert*, 9F.3d 1531, 1534 (Fed. Cir. 1993). Applicants submit that inherency may not be established by probabilities or possibilities. The missing limitation must be necessarily present in the thing described in the reference (see e.g., MPEP 2112 IV). Applicants submit that the mere possibility that Zhong et al may have a clone containing the claimed sequence is not enough for a 102 rejection based on inherency. Applicants submit that even if Zhong's library contains a clone having the claimed sequence, it is well established that a disclosed generic formula anticipates a specific species covered by the formula only if the species can be "at once envisaged" from the formula (see e.g., MPEP 2131.02). In the instant case,

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Zhong simply discloses the generation of a genomic library for zebrafish. Applicants submit that the reference does not provide the sequences of all clones, nor does it provide any guidance as to which clones contain the claimed sequence, a polynucleotide comprising a liver-specific expression control sequence from a fish that modulates expression of a vertebrate L-FABP".

Applicant's arguments filed 8/15/2006 have been fully considered but they are not persuasive.

The zebrafish library taught by Zhong et al provides 4.7-fold coverage of the zebrafish genome on yeast artificial chromosomes. Absent evidence to the contrary, a genome library that comprises the genome almost five times would comprise a fish liver-specific expression control sequence. Five copies of the fish genome would provide more than a mere possibility that all of the genomic sequences of the animal are present in the library. The teaching of Zhong et al does not have to provide the sequences of each clone in order to anticipate the claimed polynucleotide. Claim 1 is a broad claim that does not recite a specific sequence for the isolated polynucleotide comprising a liver-expression control sequence.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319,

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51 USPQ2d 1307, 1310 (Fed.Cir.1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics."); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) ("Because sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.") See MPEP 2112 II.

Therefore, the zebrafish library taught by Zhong et al would anticipate the claimed isolated polynucleotide even if the specific sequence is not taught because, absent evidence to the contrary, at least of one of the library clones would include the claimed isolated polynucleotide sequence. The issues in *In re Rijckert*, 9F.3d 1531, 1534 (Fed. Cir. 1993) is not applicable to the merit of the instant case, since the issues of *In re Rijckert* dealt with obviousness and a claimed relationship between three variables to time expansion/compression for a magnetic record carrier. In the instant case, the question at hand is whether or not a complete zebrafish genomic library would inherently contain a particular polynucleotide sequence on at least one of the clones.

Applicants submit that even if Zhong et al's library contains a clone having the claimed sequence, it is well established that a disclosed generic formula anticipates a specific species covered by the formula only if the species can be "at once envisaged" from the formula (see e.g. MPEP 2131.02). The claims are drawn to an isolated polynucleotide comprising a liver-expression control sequence from a fish, wherein the expression control sequence modulates expression of a vertebrate L-FABP. Zhong et al does not have to demonstrate functionality of the sequence because, absent evidence to the contrary the claimed fish liver-expression control sequence would be

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capable of modulating expression of a vertebrate L-FABP. Therefore, an isolated YAC library clone comprising the genomic sequence of a zebrafish would anticipate the claimed sequence.

The Declaration under 37 CFR 1.132 filed 8/15/2006 is sufficient to overcome the rejection of claims 1-3 and 12-14 based upon 35 U.S.C. § 102(a) as being anticipated by Her et al.

Applicant's arguments, see pages 15-16, filed 8/15/2006, with respect to the rejection of claims 1, 6 and 10-12 under 35 U.S.C. §102(b) have been fully considered and are persuasive. The rejection of claims 1, 6 and 10-12 over Falk et al (U.S. Patent No. 5,625,124) has been withdrawn.

Applicant's arguments, see pages 15-16, filed 8/15/2006, with respect to the rejection of claims 1, 6 and 10-12 under 35 U.S.C. §102(b) have been fully considered and are persuasive. The rejection of claims 1, 6 and 10-12 over Simon et al has been withdrawn.

Applicant's arguments, see pages 15-16, filed 8/15/2006, with respect to the rejection of claims 1, 12 and 14 under 35 U.S.C. §102(a) have been fully considered and are persuasive. The rejection of claims 1, 12 and 14 over Gerard et al (U.S. Patent No. 6,503,498) has been withdrawn.

Applicant's arguments, see pages 15-16, filed 8/15/2006, with respect to the rejection of claims 1, 6, 10 and 11-12 under 35 U.S.C. §102(e) have been fully

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considered and are persuasive. The rejection of claims 1, 6, 10 and 11-12 over Yamanouchi et al (U.S. Patent No. 6,794,154) has been withdrawn.

Applicant's arguments, see pages 15-16, filed 8/15/2006, with respect to the rejection of claims 1, 12 and 14 under 35 U.S.C. §102(e) have been fully considered and are persuasive. The rejection of claims 1, 12 and 14 over Hogaboam et al (U.S. Patent No. 6,719,969) has been withdrawn.

It is noted that Applicants have amended claims 4-6 and 8-11 to recite "the nucleotide sequence". Therefore, the rejection of claims 4-6, and 8-9 under 35 U.S.C. § 102(a) has been withdrawn.

Claims 1, 12 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank Accession No. AL929535, submitted 2/7/2003 by Tracey.

This rejection of claims 1, 12 and 14 are being maintained for reasons of record in the previous Office Action, mailed 5/16/2006 and for reasons outlined below.

Applicants submit that these sequences do not specifically disclose "an isolated polynucleotide comprising a liver-specific expression control sequence from a fish that modulates expression of a vertebrate L-FABP" as recited in claim 1, nor do they provide any guidance on how to locate such a sequence. Applicants submit that the existence of SEQ ID NOS:4-9 simply suggests that the cited sequences may contain a liver-specific expression control sequence that modulates expression of a vertebrate liver fatty acid binding protein (L-FABP). Applicants submit that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the

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inherency of the result or characteristic. *In re Rijckert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

Applicants arguments filed 8/15/2006 have been fully considered but have not been found persuasive. GenBank Accession No. AL929535 is a 162,435 base pair zebrafish DNA sequence on a clone identified as CH211-15101. Claim 1 is drawn to an isolated polynucleotide sequence comprising a liver-specific expression control sequence from a fish. The limitation of isolated polynucleotide is met because a clone vector is an isolated sequence and the instant claim does not limit the other sequences that can be present in the clone, only that the polynucleotide must comprise the liver-specific expression control sequence from a fish. The presence of sequence fragments with ~84% sequence identity to a fish liver-specific expression control sequence suggests that absent evidence to the contrary, it would modulate expression of a vertebrate L-FABP. Although Applicant submits that Gen Bank Acc. No. AL929535 does not provide any guidance on how to locate such a sequence, the instant claim does not provide any limitations on the size of the liver expression control sequence. Therefore the entire clone CH211-15101 meets the limitation of an isolate polynucleotide sequence comprising a liver-specific expression control sequence from a fish. In the instant case, the question at hand is whether or not a complete zebrafish genomic library would inherently contain a particular polynucleotide sequence on at least one of the clones. As discussed above, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. (See MPEP 2112 II).

The issues in *In re Rijckert*, 9F.3d 1531, 1534 (Fed. Cir. 1993) is not applicable to the merit of the instant case; since the issues of *In re Rijckert* dealt with obviousness and a claimed relationship between three variables to time expansion/compression for a magnetic record carrier.

Claims 1, 12 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank Accession No. AC139623, submitted 2/7/2003 by Akhter et al.

The rejection of claims 4-6 and 8-9 under 35 U.S.C. § 102(a) has been withdrawn.

This rejection of claims 1, 12 and 14 are being maintained for reasons of record in the previous Office Action, mailed 5/16/2006 and for reasons outlined below. Applicants' arguments are the same as presented for the above rejection. Applicants arguments filed 8/15/2006 have been fully considered but have not been found persuasive.

GenBank Accession No. AC 139623 is a 203,371 bp zebrafish DNA sequence on a clone identified as CH211-216G21. The claim 1 limitation of isolated polynucleotide is met because a clone is an isolated sequence and the instant claim does not limit the other sequences that can be present in the clone, only that the polynucleotide must comprise the liver-specific expression control sequence from a fish. The presence of sequence fragments with ~86% sequence identity to a fish liver-specific expression control sequence suggests that absent evidence to the contrary, it would modulate expression of a vertebrate L-FABP. Although Applicants submit that GenBank Acc. No.

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AC139623 does not provide any guidance on how to locate such a sequence, the instant claim does not provide any limitations on the size of the liver expression control sequence. Therefore the entire clone CH211-216G21 meets the limitation of an isolate polynucleotide sequence comprising a liver-specific expression control sequence from a fish.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Genbank Accession No. BX240588, submitted 1/27/2003 by Humphray et al.

The rejection of claims 4-6 and 8-9 under 35 U.S.C. § 102(a) has been withdrawn. The rejection of claim 1 is being maintained for reasons given in the Office Action mailed 5/16/2006 and for reasons outlined below.

Applicants' arguments are the same as presented for the above rejection. Applicants arguments filed 8/15/2006 have been fully considered but have not been found persuasive.

GenBank Accession No. BX240588 is a 738 bp zebrafish DNA sequence on a clone identified as DKEY-288B14. The presence of sequence fragments with ~90% sequence identify to a fish liver-specific expression control sequence suggests that absent evidence to the contrary, it would modulate expression of a vertebrate L-FABP. Although Applicant submits that GenBank Acc. No. DKEY-288B14 does not provide any guidance on how to locate such a sequence, the instant claim does not provide any limitations on the size of the liver expression control sequence. Therefore the entire

clone CH211-216G21 meets the limitation of an isolate polynucleotide sequence comprising a liver-specific expression control sequence from a fish.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem, PhD
Examiner
1/19/2006

CELINE QIAN, PH.D.
PRIMARY EXAMINER

